GE Medical Systems
OEC

GE OEC Medical Systems, Inc.
General Electric Company
384 Wright Brothers Drive, Salt Lake City, UT 84116-2862
http://www.gemedicalsystems.com

MAR 1 2 2001

K003837

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date:	December 5, 2000
Name of Submitter:	GE OEC Medical Systems 384 Wright Brothers Drive Salt Lake City, UT 84116 801-328-9300
Corresponding Official:	Ted L. Parrot, Vice President, Quality Assurance & Regulatory Affairs
Device Proprietary Names:	(1) Series 7800 Mobile C-Arm (2) Compact 7800 Mobile C-Arm (3) Compact 7800 Plus Mobile C-Arm
Classification Name:	Image Intensified Fluoroscopic X-ray System
Common/Usual Names:	Fluoroscopic Imaging System or Mobile C-Arm
Substantial Equivalence:	The Series 7800, Compact 7800 and Compact 7800 Plus C-Arms are substantially equivalent to the Series 9800 Mobile Digital Imaging System (K974355) marketed by GE OEC Medical Systems.

Indications for Use

The Series 7800, Compact 7800 and Compact 7800 Plus Mobile C-Arms are designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic and surgical procedures. Clinical applications include but are not limited to general surgery, gastro-intestinal, urologic, orthopedic, neurologic, vascular, and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

General Description

The 7800 will be a mobile monoblock C-arm offered in 3 main configurations:

1) The Series 7800 will provide basic fluoroscopic and optional vascular imaging capabilities for general intraoperative and peripheral vascular applications.

   It will consist of two components: mobile C-arm mainframe and mobile 1k x 1k workstation. The image processor will reside in the workstation.

2) The Compact 7800 will consist of a mobile C-arm mainframe with an articulated support arm mounted to the horizontal cross-arm assembly. The support arm will support a single display monitor. The monitor will swivel on the support arm to direct the image display from the surgeon's viewpoint at either side of the image intensifier to the technologist's viewpoint at the rear of the mainframe.

   In addition, a swivel-mounted flat panel touch screen monitor (approximately 7" diagonal) will attach beneath the viewing monitor to provide a view to the operator positioned at the C-arm controls.

   A 1k x 1k image processor will reside in the C-arm mainframe.

3) The Compact 7800 will operate either independent of a workstation for simpler applications or attach to a 1k x1k workstation where additional image memory, processing, or hardcopy options are required. When a Compact 7800 is attached to a 1k x 1k workstation, the system configuration will be referred to as the Compact Plus. This configuration will provide more advanced capabilities such as additional image storage, image processing (DSA, Roadmap, etc), cine capabilities, and left-to-right monitor swap.

User Characteristics

The 7800 C-Arm product family is used by health care professionals such as physicians, surgeons, radiologists and x-ray technologists in hospitals, outpatient clinics and other clinical care environments. Users are trained by qualified applications and service specialists in the proper use of the equipment. The device labeling stipulates that only properly trained persons operate the equipment.

Product Standards

The 7800 C-Arm product family is designed in accordance with product safety and performance requirements established in the following standards:

21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems
ANSI/NFPA 70 & 99	National Electrical Code and Standard for Health Care Facilities
UL 2601	Medical Electrical Equipment
CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment
IEC 60601-1	Medical Electrical Equipment, General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment, Electromagnetic Compatibility
IEC 60601-1-3	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray
IEC 60601-1-4	Medical Electrical Equipment, Programmable Electrical Medical Systems
IEC 60601-2-7	Medical Electrical Equipment, HV/X-ray Generators
IEC 60601-2-28	Medical Electrical Equipment, X-ray Tube and Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment, Safety of Associated X-ray Equipment
93/42/EEC - Annex 1	Essential Requirements of the Medical Devices Directive

This concludes this 510(k) Summary.

GE OEC MEDICAL SYSTEMS

Ted L. Parrot,
Vice President, Quality Assurance & Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2001

Ted L. Parrot
Vice President, Quality Assurance/Regulatory Affairs
and Official Correspondent
GE OEC Medical Systems, Inc.
384 Wright Brothers Drive
SALT LAKE CITY UT 84116-2862

Re: K003837
Series 7800 Mobile C-Arm; Compact 7800 Mobile C-Arm; and Compact 7800 Plus Mobile C-Arm
Dated: December 5, 2000
Received: December 12, 2000
Regulatory Class: II
21 CFR 892.1720 and 21 CFR 892.1650
Procode: 90 IZL and 90 JAA

Dear Mr. Parrot:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications For Use Statement

Applicant: GE OEC Medical Systems

510(k) No. (if known): K003837

Device names: (1) Series 7800 Mobile C-Arm
(2) Compact 7800 Mobile C-Arm
(3) Compact 7800 Plus Mobile C-Arm

Indications for use: The Series 7800, Compact 7800 and Compact 7800 Plus Mobile C-Arms are designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic and surgical procedures. Clinical applications include but are not limited to general surgery, gastro-intestinal, urologic, orthopedic, neurologic, vascular, and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003837

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)